K123869

FEB 2 8 2013

510 (K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification:**

Dehai (Shandong) Medical Gloves, Co., Ltd.
No. 216 Huangong Road
Linzi District, Zibo, Shandong
China

Contact Person: Ray Zhou
Tel: 909-548-4828
Fax: 909-548-4807
Email: rayzhou@basicmedical.com

Date summary prepared: Feb. 5, 2013

2. **Name of the Device:**

Dehai (Shandong) Medical Gloves, Co., Ltd.
Nitrile Examination Gloves – Powder Free, Blue Color

3. **Predicate Device Information:**

Tangshan Zhonghong Pulin Group Co., Ltd.
Synthetic Nitrile Patient Examination Gloves – Powder Free (K082598)

4. **Device Description:**

Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free Nitrile Patient Examination Glove, 80LZA, and meets all requirement of ASTM Standard D6319-10.

5. **Intended Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250)

6. **Comparison to Predicate Devices:**

Dehai (Shandong) Medical Gloves, Co., Ltd. powder-free nitrile examination gloves (subject device) and Tangshan Zhonghong Pulin Group Co., Ltd. powder-free nitrile examination glove (predicate device) are substantially equivalent in all technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole. (please kindly refer attached side-by-side comparison of intended use, design, material, physical, biocompatibility and performance testing, Table 7-2)

7. **Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:**

The standards used for Dehai (Shandong) Medical Gloves, Co., Ltd. glove production are based on ASTM-D-6319-10. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AOL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AOL 2.5, Inspection Level I, meeting these requirements, Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per glove).

8. **Discussion of Clinical Tests Performed:**

Not Applicable – There is no hypoallergenic claim.

9. **Conclusions:**

Dehai (Shandong) Medical Gloves, Co., Ltd. Nitrile Patient Examination Gloves, Powder-Free, Blue color, conform fully to ASTM-D-6319-10 standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

Table 7-2. Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing

	Proposed Device	Predicate Device (K082598)
Description	Dehai (Shandong) Medical Gloves, Co., Ltd. Powder-Free Nitrile Examination Gloves, Blue color	Tangshan Zhonghong Pulin Group Co., Ltd. Powder Free Nitrile Patient Examination Gloves
Labeling: Instruction for use	A garment covering the hand and wrist area. Clovers have separate sheaths or openings for each finger and the thumb.	Substantially equivalent
Labeling: Labels on the carton	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor name, and manufacturer address.	Substantially equivalent
Device Materials	Nitrile Latex (NBR) Sulfur Accelerator, ZDBC Zinc Oxide Potassium Hydroxide Titanium Dioxide and Stabilizer	Substantially equivalent
Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 29.00 Average Ultimate Elongations: 750%	Substantially equivalent
After Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 24.00 Average Ultimate Elongations: 700%	Substantially equivalent
Overall Length on Medium Size	Average over 230mm	Substantially equivalent
Width of Palm on Medium Size	Average 95mm	Substantially equivalent

Palm Thickness	Average 0.073 mm	Substantially equivalent
Figure Thickness	Average 0.090 mm	Substantially equivalent
Residual Powder	According to ASTM D6124-06 Standard Test Method for Residual Powder on Medical gloves for the determination of residual powder content. Testing result indicates the weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found according to ASTM D6124-06.	Substantially equivalent
Pinhole Results	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	Substantially equivalent
Biocompatibility Result: Primary Skin Irritation	ISO 10993-10 passes	Substantially equivalent
Dermal Sensitization	ISO 10993-10 passes	Substantially equivalent
Summary of comparison	Dehai (Shandong) Medical Gloves, Co., Ltd. powder-free nitrile examination gloves (subject device) and Tangshan Zhonghong Pulin Group Co., Ltd. powder-free nitrile examination glove (predicate device) are substantially equivalent in all technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

Dehai (Shandong) Medical Gloves, Company, Limited
C/O Mr. Ray Zhou
President
Basic Medical Industries, Incorporated
12390 East End Avenue
CHINO CA 91710

Re: K123869
Trade/Device Name: Patient Nitrile Examination Gloves, Powder Free, Non-Sterile, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: November 10, 2012
Received: December 17, 2012

Dear Mr. Zhou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

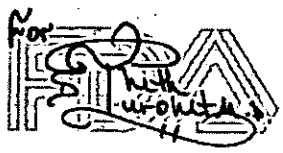
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123869

Dehai (Shandong) Medical Gloves, Co., Ltd.
No. 216 Huangong Road, Linzi District, Zibo, Shandong, China
Tel: 8618905331363

INDICATIONS FOR USE

Applicant: Dehai (Shandong) Medical Gloves, Co., Ltd.

510(k) Number: K123869

Device Name: Patient Nitrile Examination Gloves, Powder free, Non-Sterile, Blue Color

Indications of Use:

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250)

Prescription Use _____ Over the Counter Use ___X___

Factory Initials _____

Elizabeth F. Claverie
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123869